

Draft Guidance on Allocating and Targeting Pandemic Influenza Vaccine

Introduction

Effective allocation of vaccines will play a critical role in preventing influenza and reducing its effects on health and society when a pandemic arrives. The specific type of influenza that causes a pandemic will not be known until it occurs. Developing a new vaccine in response will take several months and pandemic vaccine may not be available when cases first occur in the United States. Moreover, once vaccine production begins, it will not be possible to make enough new vaccine to protect everyone in the early stages of a pandemic.

The U.S. Government is taking steps to minimize the need to make vaccine allocation decisions by supporting efforts to increase domestic influenza vaccine production capacity. Significant funding is being provided to develop new vaccine technologies that allow production of enough pandemic influenza vaccine for any person in the United States who wants to be vaccinated within six months of a pandemic declaration. Until this goal is met, Federal, State, local and tribal governments, communities, and the private sector will need guidance on who should be vaccinated earlier during the pandemic to best protect our people, communities, and country.

Issues to consider in drafting guidance on pandemic influenza vaccination are different and more complex than in developing recommendations for vaccination against annual influenza. In contrast with annual influenza, during a pandemic nobody in the population is likely to have immunity to the virus, many more people will become ill, and rates of severe illness, complications and death are likely to be much higher and more widely distributed throughout the population. The greater frequency and severity of disease will increase the burden on health care providers and institutions and may disrupt critical products and services in health care and other sectors. National and homeland security could be threatened if illness among military and other critical personnel undermines their capabilities. Because the needs that must be addressed by pandemic vaccination differ from annual influenza vaccination, the guidance on vaccination differs as well.

This draft guidance is intended to provide strong advice to support planning an effective and consistent pandemic response by States and communities. Nevertheless, it is important that plans are flexible as the guidance may be modified based on the status of vaccine technology, the characteristics of pandemic illness, and risk groups for severe disease – factors that will remain unknown until a pandemic actually occurs.

The Federal Government has embarked on a rigorous and collaborative process that seeks input from all interested parties in developing this strategy. Hearing opinions from persons and organizations with a wide variety of interests and concerns is the best way to ensure that allocation of vaccine in the early stages of a pandemic is fair and provides the best chance for our country to emerge from a pandemic with minimal levels of illness, death, and disruption to our society and economy.

Public and stakeholder input have been central to the development of this draft guidance and will continue to be crucial as the guidance is finalized. Comments received on this draft guidance

will be considered by a Federal Government working group made up of members of various U.S. Government agencies, and will contribute to a final guidance document. Comments on this draft strategy will be solicited through:

- Public meetings,
- Stakeholders meetings,
- Web-based public dialogue, and
- A request for comments posted at www.pandemicflu.gov and in the *Federal Register*.

Vaccination will be only one of several tools that can be used to fight the spread of influenza when a pandemic emerges. Other approaches include public health measures in communities, businesses, and households to reduce and slow the spread of infection; using antiviral medications for treatment and prevention; and washing hands and covering coughs and sneezes. These strategies will be the initial mainstay of a pandemic response before vaccine is available and continue to have important effects as vaccination availability progresses. Guidance around vaccine use is meant to be applied in conjunction with and in the context of these other pandemic response efforts. More information about pandemic planning and response measures is provided at www.pandemicflu.gov.

How the Draft Guidance was Developed

This guidance was drafted by a Federal interagency working group whose members represent all sectors of the government. The draft guidance is firmly rooted in the most up-to-date scientific information available, and directly considers the values of our society and the ethical issues involved in planning a phased approach to pandemic vaccination. Information considered by the working group included rigorous scientific assessments of pandemics and pandemic vaccines, national and homeland security issues, essential community services and the infrastructures and workforces critical to maintaining them, and the perspectives of state and local public health and homeland security experts. Historical analysis of the influenza pandemics of 1918, 1957, and 1968 and their effects provided valuable insights to this draft guidance. Ethical considerations presented by an ethicist who served on the working group and by academic ethicists also were important to the working group process and deliberations.

Meetings with the public and stakeholders, including businesses and community organizations, provided key input on public values and priorities. Participants discussed and rated the importance of potential vaccination program objectives based on a severe pandemic scenario. Notably, each of the meetings came to the same conclusions about which program objectives are most important (outlined in the next section).

A formal decision-analysis process also was undertaken that considered the objectives of a pandemic vaccination program and the degree to which protecting population groups (defined by their occupation, age, and health status) contributed to meeting those objectives. Based on this process, groups that ranked highest were front-line public health responders, essential health care workers, emergency medical service providers, and law enforcement personnel. Among the general population groups, infants and toddlers ranked highest.

For additional information on the draft guidance development process, please refer to Appendix A.

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Goals and Objectives

The *goal* of the pandemic influenza vaccination program is to vaccinate all persons in the United States who choose to be vaccinated.

It is recognized that vaccine supply to meet this goal will likely not be available all at once, but rather, develop at varying rates depending on both vaccine characteristics (antigen required) and production capacity. Given that influenza vaccine supply will increase incrementally as vaccine is produced during a pandemic, allocation decisions will have to be made. Such decisions should be based on publicly articulated and discussed program objectives and principles. The overarching objectives guiding vaccine allocation and use during a pandemic are to reduce the impact of the pandemic on health and minimize disruption to society and the economy.

One of the most important findings of the working group analysis, and the strongest message from the public and stakeholder meetings, was that there is no single, overriding objective for pandemic vaccination and no single target group to protect at the exclusion of others. Rather, there are several important objectives and, thus, vaccine should be allocated simultaneously to several groups. Each of the meetings came to the same conclusions about which program *objectives* are most important:

- Protecting those who are essential to the pandemic response and provide care for persons who are ill,
- Protecting those who maintain essential community services,
- Protecting children, and
- Protecting workers who are at greater risk of infection due to their job.

In addition to these, working group discussions highlighted the important Federal objective of maintaining homeland and national security.

General Guidance on Pandemic Vaccination

General guidance of the working group includes the following:

- The need to target vaccine to maintain security, health care, and essential services will depend on how severe the pandemic is, as rates of absenteeism and the ability to supply essential products and services will differ between more and less severe pandemics. As a result, groups targeted for earlier vaccination will differ by pandemic severity.
- Allocation of pandemic vaccines to States will be in proportion to the State's population.
- Whereas States should follow the national guidance, they will have some flexibility in defining the target groups and implementing the guidance to best fit their local situations.
- Within the parameters of the guidance, a small proportion of each State's vaccine allocation may be maintained at the State level for distribution based on the specific needs of that jurisdiction.

- In past pandemics, groups at increased risk for serious illness and death have differed by age and health status. Because the high-risk groups in the next pandemic are not known, this guidance will be reassessed and may be modified at the time of the pandemic.
- Guidance on pandemic vaccine allocation and targeting will be re-assessed periodically to consider the potential impacts of new scientific advances, changes in vaccine production capacity, and advances in other medical and public health measures.

Framework for Targeting Pandemic Influenza Vaccine

Guidance for targeting vaccination was developed in a structure that defines target groups in four broad *categories* – people who: 1) protect homeland and national security, 2) provide health care and community support services, 3) maintain critical infrastructure, and 4) are in the general population.

Within categories, vaccination target groups are clustered into *levels*. In general, all groups within a category and level will have the same priority for vaccination. Within a category, levels are listed in descending order of priority for vaccine. Levels across categories are not necessarily comparable in terms of vaccine prioritization.

Allocation and targeting of vaccine integrating categories occurs in *tiers*. By design, groups in a tier (cutting across categories) are vaccinated simultaneously unless vaccine supply is so limited that sub-prioritization is needed. Finally, groups in vaccination tiers differ depending on *pandemic severity*, defined as severe, moderate, and less severe as described in the Pandemic Severity Index.

Guidance Framework At-A-Glance

Target Groups – People targeted for vaccination defined by a common occupation, type of service, age group, or risk level.

Categories – Pandemic vaccination target groups are clustered into four broad categories (homeland and national security, health care and community support services, critical infrastructures, and the general population). These four categories together cover the entire population.

Levels – Within individual categories, groups are clustered into levels which correspond to vaccination priority within that specific category.

Tiers – Across categories, vaccine will be allocated and administered according to tiers where all groups designated for vaccination within a tier have equal priority for vaccination. Groups within tiers vary depending on pandemic severity.

The Pandemic Severity Index (PSI)

The Pandemic Severity Index defines categories of pandemic severity based on the proportion of individuals with pandemic illness who die (the “case fatality rate”). Pandemic severity will be determined soon after its initial outbreak based on surveillance of cases and their outcomes before large areas of the world are affected. Government organizations will use the PSI to determine how best to implement responses such as vaccination and community strategies to reduce disease transmission. For a diagram and additional information on the PSI, please refer to Appendix B.

Pandemic Vaccination Categories and Levels within Each Category

Target groups for pandemic vaccination are defined in four categories corresponding to major objectives of the pandemic vaccination program, which are to protect:

- Homeland and National Security,
- Health Care and Community Support Services,
- Critical Infrastructures, and the
- General Population.

Everyone in the United States is included in at least one of these categories. Where persons are included in more than one category, defined by their occupational role as well as their age and health status, they would be targeted for vaccination with the earliest group in which they are included.

Groups within each category are clustered into priority “levels” based on national pandemic response and vaccination program goals (Table 1). Within each category, groups in level A will receive vaccine first, in general followed by those in levels B, C, D, and E. All groups included in the same level within a vaccination category have equal priority. The exceptions are in the General Population, Level B, where because of the large number of children, sub-prioritization is proposed, and in Level C where younger persons would be targeted first when vaccine supply is very limited because of the greater vaccine effectiveness in this group.

Vaccination target groups in the Homeland and National Security, Health Care and Community Support Services, and Critical Infrastructure categories include *only persons who are deemed critical to provide services that are essential to maintain during a pandemic, not the entire workforce*. Identification of the functions considered to be “critical” was partly based on an analysis of critical sectors and workforces conducted by the U.S. Department of Homeland Security’s National Infrastructure Advisory Council (NIAC) (www.dhs.gov/niac), along with input from Federal agencies. Because a pandemic differs from other national emergencies in the threats it poses and the duration over which it will affect our nation and communities, target groups within each sector may be different from those defined in other emergency response planning. Further work is being undertaken to more specifically define critical occupations whose members should receive early vaccination.

It should be emphasized that the primary objective of vaccinating persons in critical infrastructure sectors is *not* to reduce absenteeism generally, through an incremental reduction in

pandemic illness afforded by vaccination. Rather, vaccination is targeted to protect workers with critical skills, experience, or licensure status whose absence would create bottlenecks or collapse of critical functions, and to protect workers who are at especially high occupational risk. Other pandemic response strategies (e.g., avoiding close contact with others, use of personal protective equipment such as facemasks, good handwashing, etc.), and worker education are likely to have greater overall effects in decreasing absenteeism.

For additional information on the definition of groups in each category, the rationales for how groups are ordered, and the estimated size of the target population, please refer to Appendix C.

Table 1. Categories and target groups for pandemic vaccination (see Appendix C for more specific definitions of priority groups and rationales). In each category, levels cluster target groups having a similar priority for vaccination. Occupation-based groups include only persons deemed essential to support the critical functions of the group. All persons in the United States are included in at least one targeted group.

LEVEL	Homeland & National Security (HNS)
A	<ul style="list-style-type: none"> ○ Deployed and mission critical personnel
B	<ul style="list-style-type: none"> ○ Essential support and sustainment personnel ○ Intelligence services ○ Border protection personnel ○ National Guard personnel (who are not already included in Level A) ○ Other domestic national security personnel
C	<ul style="list-style-type: none"> ○ Remaining active duty military and essential support personnel

LEVEL	Health Care & Community Support Services (HC/CSS)
A	<ul style="list-style-type: none"> ○ Public health personnel ○ Inpatient health care providers ○ Outpatient and home health care providers ○ Health care providers in long-term care facilities (LTCFs)
B	<ul style="list-style-type: none"> ○ Community support services and emergency management personnel
C	<ul style="list-style-type: none"> ○ Other important health care personnel

LEVEL	Critical Infrastructure (CI)
A	<ul style="list-style-type: none"> ○ Emergency Medical Services personnel ○ Law enforcement personnel ○ Fire services personnel ○ Manufacturers of pandemic vaccine, antiviral drugs, and other key pandemic response materials ○ Key government leaders
B	<ul style="list-style-type: none"> ○ Energy sector personnel (electricity and natural gas) ○ Communications personnel (telephony and IT) ○ Water sector personnel (potable and waste water) ○ Government personnel
C	<ul style="list-style-type: none"> ○ Transportation sector personnel ○ Food and agriculture sector personnel ○ Banking and finance sector personnel ○ Pharmaceutical sector personnel ○ Chemical sector personnel ○ Oil sector personnel ○ Postal and shipping sector personnel ○ Other important government personnel

LEVEL	General Population (GP)
A	<ul style="list-style-type: none"> ○ Pregnant women ○ Infants and toddlers, 6 – 35 months old
B	<ul style="list-style-type: none"> ○ Household contacts of infants under 6 months old ○ Children 3 – 18 years old with high-risk medical conditions ○ Children 3 – 18 years old without high-risk medical conditions
C	<ul style="list-style-type: none"> ○ High risk persons 19 – 64 years old ○ Persons 65 years and older
D	<ul style="list-style-type: none"> ○ Healthy adults, 19 – 64 years old, not included in other categories

Integrating Priorities for Pandemic Vaccination in Pandemics of Different Severity

Recognizing the need to address several important objectives for a pandemic vaccination program, vaccine should be allocated simultaneously to target groups across categories. To do so, target groups from different categories are integrated into tiers for vaccination.

The order in which target groups in Table 1 are vaccinated is defined separately for severe, moderate, and less severe pandemics (see Table 2). All groups designated for vaccination within a tier have equal priority for vaccination (see Figure 1 as an example of vaccination tiers for a severe pandemic). In general, vaccine allocation within a tier will be proportional to the populations of the targeted groups, though changes in this allocation scheme at the time of the pandemic may occur based on the impacts of the pandemic and the specific needs identified at that time.

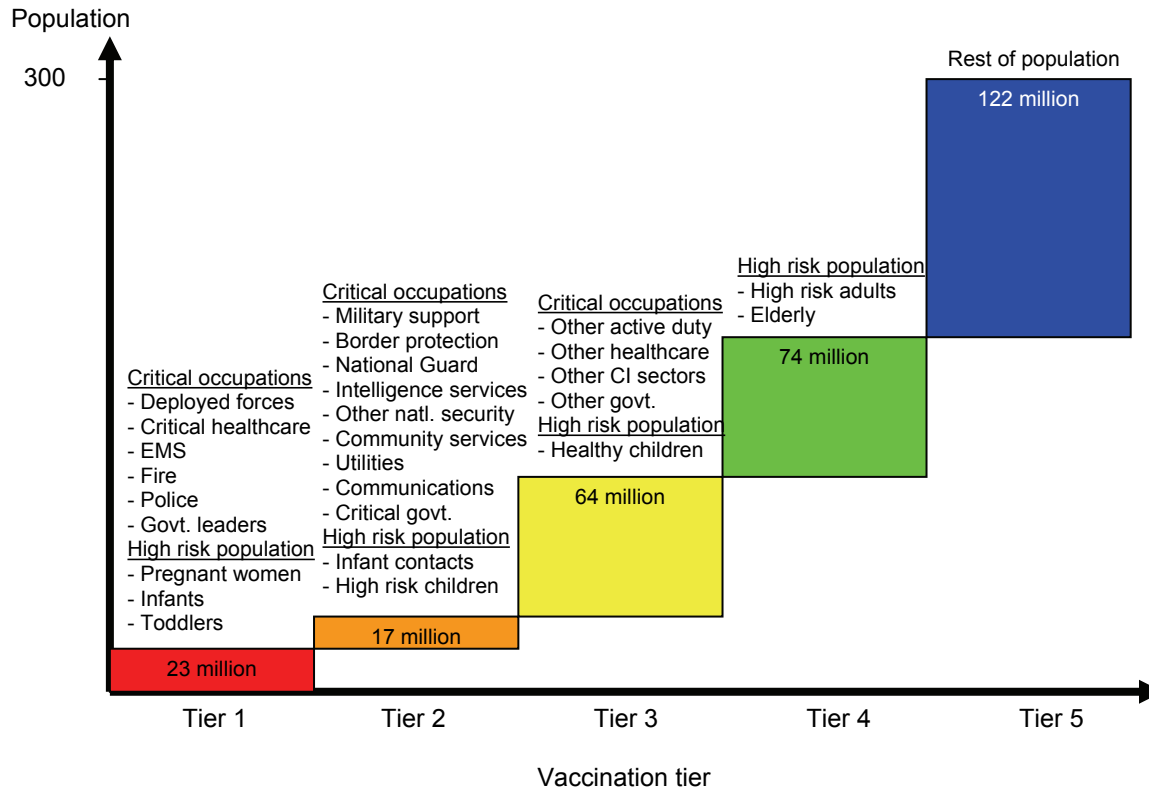
Defining vaccination tiers differently by pandemic severity reflects differences in the threats more or less severe pandemics pose to society and individuals. Pandemics with higher case fatality rates are more likely to disrupt essential services, increase workplace absenteeism (due to illness, caring for family members, or to decrease risk of exposure), threaten public order and homeland security, and disrupt international and domestic supply chains compared with less severe pandemics. Thus, tailoring strategies to pandemic severity will best achieve national pandemic response goals and objectives. Pandemics are defined as “severe” (PSI categories 4 or 5), “moderate” (PSI category 3), and “less severe” (PSI categories 1 and 2).

It should be noted that members of occupational target groups are defined by the functions individuals within that target group are anticipated to perform over an extended period of time during the pandemic outbreak; it does not distinguish among staff performing these duties as part of their usual functions, those being reassigned to perform the function as a new response role, or those performing the function as a volunteer. It should also be noted that vaccine does not replace, but adds to other measures taken to protect the workforce and general population.

Table 2. Vaccination target groups, estimated populations, and tiers for severe, moderate and less severe pandemics as defined by the Pandemic Severity Index (PSI).

	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Not targeted	
Category	Target group	Estimated number	Severe	Moderate	Less severe		
Homeland and national security	Deployed and mission critical pers.	700,000	Tier 1	Tier 1	Tier 1		
	Essential support & sustainment pers.	650,000	Tier 2	Tier 2	Tier 2		
	Intelligence services	150,000					
	Border protection personnel	100,000					
	National Guard personnel	500,000					
	Other domestic national security pers.	50,000					
Other active duty & essential suppt.	1,500,000	Tier 3	Tier 3	Not targeted			
Health care and community support services	Public health personnel	300,000	Tier 1	Tier 1	Tier 1		
	Inpatient health care providers	3,200,000					
	Outpatient and home health providers	2,000,000					
	Health care providers in LTCFs	800,000	Tier 2	Tier 2	Not targeted		
	Community suppt. & emergency mgt.	600,000					
Other important health care personnel	500,000	Tier 3	Tier 3	Not targeted			
Critical infrastructure	Emergency Medical Service personnel	2,000,000	Tier 1	Tier 1	Tier 1		
	Law enforcement personnel						
	Fire services personnel						
	Mfrs of pandemic vaccine & antivirals						50,000
	Key government leaders						50,000
	Electricity sector personnel	1,900,000 to 4,400,000	Tier 2	Tier 2	Not targeted		
	Natural gas personnel						
	Communications personnel						
	Water sector personnel						
	Critical government personnel						
Transportation sector personnel	1,400,000 to 3,500,000	Tier 3	Not targeted	Not targeted			
Food and agriculture sector personnel							
Banking and finance personnel							
Pharmaceutical sector personnel							
Chemical sector personnel							
Oil sector personnel							
Postal and shipping personnel							
Other important government personnel							
General population	Pregnant women	3,100,000	Tier 1	Tier 1	Tier 1		
	Infants & toddlers 6–35 mo old	10,300,000	Tier 2	Tier 2	Tier 2		
	Household contacts of infants < 6 mo	4,300,000					
	Children 3–18 yrs with high risk cond.	6,500,000	Tier 3	Tier 2	Tier 3		
	Children 3–18 yrs without high risk	58,500,000					
	Persons 19–64 with high risk cond.	36,000,000					
	Persons ≥65 yrs old	38,000,000	Tier 4	Tier 3	Tier 2		
Healthy adults 19–64 yrs old	121,800,000	Tier 5	Tier 4	Tier 4			

Figure 1. Vaccination tiers and target groups for a severe pandemic. This figure illustrates how vaccination is administered by tiers until the entire U.S. population has had the opportunity to be vaccinated, and how tiers integrate target groups across the four categories balancing vaccine allocation to occupationally defined groups and the general population.



Vaccination Tier 1 at All Pandemic Severities

Tier 1 includes the highest priority groups (Level A) identified in each of the four categories (Table 2). Unlike other tiers which differ with severity of the pandemic, Tier 1 is the same across all pandemic severities. This is because for the occupationally defined groups in this tier, maintaining effectiveness is critical, burdens are likely to be markedly increased in any pandemic, and risk of occupational exposure and infection is high because of contact with ill persons, living conditions, or geographic location. It should be noted that during the 1918 pandemic, more American soldiers died of illness than in combat during the First World War.

Targeting vaccinations in Tier 1 to groups that serve important societal needs is balanced by including in this tier pregnant women and infants who are at high risk of dying during a pandemic. Protecting pregnant women and infants is in keeping with priorities expressed by public and stakeholder groups and is an efficient use of vaccine because a pregnant woman will pass on protection to her newborn and because infants between 6 and 35 months old may need a smaller vaccine dose compared with older persons.

Potential sub-prioritization of Tier 1

Vaccine may be in extremely short supply through the first wave of a pandemic and even longer. Particularly in a severe pandemic, it may be necessary to sub-prioritize vaccination of groups included in Tier 1 by stratifying *within* and *between* target groups (Table 3). For example, hospital-based health care providers are separated into “front-line” providers – those essential for maintaining emergency departments and intensive care units and providing medical and nursing care on inpatient wards – and other inpatient health care providers who would receive vaccine later in Tier 1. This proposed ranking of groups within Tier 1 balances allocation to achieve multiple pandemic response goals and protects persons who are at highest occupational risk of becoming infected.

Table 3. Proposed sub-prioritization of vaccination among Tier 1 target groups for situations where vaccine supply is most limited.

Priority	Group	Rationale	Estimated Population
1	Front-line inpatient and hospital-based health care workers (persons essential for maintaining function in emergency departments, intensive care units, and other front-line medical and nursing staff)	Critical role in providing care for the sickest persons; highest risk of exposure and occupational infection	1,000,000
2	Deployed and mission-critical personnel	Essential role in national and homeland security; high risk due to living conditions and possibly geographic location	700,000
3	Front-line Emergency Medical	Provide critical medical care	800,000

	Service personnel (those providing patient assessment, triage, and transport).	including procedures such as intubation that increase risk of aerosol exposure and occupational infection	
4	Front-line outpatient health care providers (physicians, nurses, respiratory therapy; includes public health personnel who provide outpatient care for underserved groups)	Effective outpatient care is critical to decrease the burden on hospitals; high risk of exposure and occupational infection	1,000,000
5	Front-line fire and law enforcement personnel	Essential to public order and safety; less substantial and more predictable risk of exposure.	1,000,000
6	Pregnant women and infants 6-11 months old	High-risk documented in prior pandemics and annually; reflects public values to protect children; vaccination of a pregnant woman also will protect the infant; infants 6-11 months old are at high-risk and antiviral drugs are not FDA-approved for children <1 year old	5,150,000*
7	Others in Tier 1 (includes Tier 1 health care workers not vaccinated previously in hospitals, outpatient settings, home health, long-term care facilities, and public health; emergency service providers; manufacturers of pandemic vaccine, antiviral drugs, and other key pandemic response materials; and children 12-35 months old)	Includes persons in critical settings who have less exposure and toddlers who are less at risk of severe disease or death than younger infants and who are able to receive antiviral treatment based on FDA approval of antiviral drugs	13,100,000**

*Because infants would be expected to receive one-half a regular vaccine dose, the number of adult vaccine dose-equivalents for this group would be about 4,125,000

**Toddlers 12 – 35 months old may receive a lower vaccine dose; thus, the number of adult vaccine dose-equivalents for this group would be less.

Vaccination Tier 2 through 5 by Pandemic Severity

In contrast with Tier 1, target groups included in Tiers 2 through 5 will be different depending on pandemic severity (see Table 2). When vaccination has been completed for all five tiers, at any pandemic severity, everyone in the United States will have had the chance to be vaccinated.

Guidance for severe pandemics (PSI 4 or 5)

Tier 2 targets groups in the Homeland and National Security category that are critical to maintaining our country's safety. Critical community support service personnel are prioritized because they are needed to assist in a community pandemic response and support the elderly, persons living alone, and families complying with voluntary quarantine when a family member is ill (recommended as part of the community mitigation strategy). Critical infrastructures targeted in Tier 2 are those that provide "just in time services" (i.e., products like electricity and natural gas that cannot be stored), are relied on by all other infrastructures for their essential operations, and contribute to public health and safety. The highest risk children – those who have underlying medical conditions that increase their risk of complications or death from influenza infections – also are included in this tier.

Tier 3 includes the remainder of target groups that protect homeland and national security, provide health care, and maintain critical infrastructures. Critical Infrastructure sectors targeted in Tier 3 are those that provide essential products and services where there generally is greater "redundancy" in infrastructure (e.g., there are many bakeries, dairies, gas stations) or personnel (e.g., there are many truck drivers); or where burden is likely to decrease in a pandemic (e.g., less demand for mass transit, postal, and shipping). Many businesses in these sectors can take other measures to protect employees, such as using alternate work schedules, teleworking, and reducing in-person meetings and other contacts in the workplace. In the general population, children without high-risk medical conditions are targeted in this tier.

Tiers 4 and 5 are focused on groups in the general population that have not yet been vaccinated. Whereas persons aged 19 to 64 years who have underlying medical conditions and elderly persons 65 years old or older are targeted in Tier 4, in situations of limited vaccine supply, the 19 to 64 year old group should be targeted first. The rationale for targeting younger persons is that the effectiveness of seasonal and candidate pandemic influenza vaccines is less among elderly persons because of age-related decreases in immune function. Thus, when vaccine supply is limited, targeting high-risk adults before the elderly makes best use of the supply that is available. Other strategies, including hygiene and public health measures to reduce the risk of infection, and treatment with antiviral medications are effective options to protect the elderly. Healthy adults would be targeted in Tier 5.

Guidance for moderate pandemics (PSI 3)

Moderate pandemics also pose threats to maintaining effective security, health care and community support services, and critical infrastructure. While target groups in Tier 1 are the same as for severe pandemics, in later tiers, general population groups assume greater priority.

Target groups in Tier 2 for homeland and national security, health care and community support services, and critical infrastructure are the same as for a severe pandemic (Table 2). However, for moderate pandemics this tier includes all children 3 to 18 years old rather than only those with high-risk medical conditions (in addition to household contacts of young infants). Because of the large population of children, if vaccine supply is limited, children with medical conditions that increase their risk of severe illness should be vaccinated before those without such conditions.

Tier 3 includes the remainder of target groups that protect homeland and national security, and provide health care. Vaccination is not targeted to critical infrastructure personnel in the remaining sectors because of the lower risk to maintenance of important functions, redundancy of infrastructures and personnel, and the ability to protect workforces using other measures: in a moderate pandemic, target groups listed in Level C of the Critical Infrastructure category would be vaccinated in their applicable age and health status group along with the general population. This tier also includes persons aged 19 to 64 years who are at higher risk of severe illness due to medical conditions and persons 65 years old and older. As for severe pandemics, if vaccine supply is limited the high-risk adults should be targeted before the elderly because of the greater vaccine effectiveness in the former group. Healthy adults are included in Tier 4.

Guidance for less severe pandemics (PSI 1 or 2)

Less severe pandemics pose less threat to delivery of health care, community support, and other essential services and products. While target groups in Tier 1 are the same as for severe pandemics, in later vaccination tiers, general population groups assume greater priority. Historical analysis of the 1957 and 1968 pandemics in the United States indicates that health care and essential services were effectively maintained. Because of this, after Tier 1, occupational groups in the health care and community support services and critical infrastructure categories are not specifically prioritized and workers in these groups would be vaccinated based on their age and health status as part of the general population.

Tier 2 includes groups that protect homeland and national security given the overriding importance of protecting our country's safety (Table 2). In contrast with more severe pandemics where children are vaccinated before other general population groups, in less severe pandemics, guidance for priority vaccination follows recommendations for annual influenza vaccination as defined by the Advisory Committee for Immunization Practices. The rationale is that a PSI category 1 pandemic may be little different than a bad annual influenza outbreak. Thus, Tier 2 includes household contacts of infants less than 6 months old and persons with medical conditions that increase their risk for influenza complications, and persons aged 65 years and older.

Tier 3 includes healthy children and Tier 4 includes healthy adults, who comprise the remainder of the population.

Next Steps and What States and Communities Can Do

This draft guidance represents the results of careful and rigorous consideration of scientific data, historical analyses, ethical issues, and comments from government agencies, key stakeholders at the national, State, and local/community levels, and members of the general public. However, this process is not complete. A national dialogue on these issues must continue before a final guidance can be issued. As a result, the U.S. Government will seek input via public meetings, stakeholder meetings, the Internet, and in an official request for comments.

The likelihood of success of any vaccination or community-based strategy is significantly enhanced by community and public input and support. Thus, members of the general public are

encouraged to learn more about this process and provide input by visiting www.pandemicflu.gov. Information also will be posted to this Web site regarding upcoming public engagement meetings and on-line discussions.

Appendix A

Additional Information on the Draft Guidance Development Process

This guidance was drafted by a Federal interagency working group whose members represent all sectors of our government. The draft guidelines are firmly rooted in the most up-to-date scientific information available, balanced with the values of our society and the ethical issues involved in planning a phased approach to pandemic vaccination.

In a series of weekly meetings over a three month period, working group members were informed on the science of pandemics and pandemic vaccine, including the effects of past pandemics; risk groups for severe influenza illness and death; influenza vaccine production, timing, and capacity; vaccine effectiveness in various population groups; potential indirect effects of vaccination on preventing the spread of disease in communities (“herd immunity”); and potential strategies and impacts for other pandemic response measures. Representatives from the U.S. Department of Defense and the U.S. Department of Homeland Security (DHS) presented to the working group on critical issues for national and homeland security. State and local public health and homeland security officials presented perspectives on community needs. Planners from Canada and the United Kingdom described their vaccine allocation plans. The group reviewed and discussed recommendations from Federal advisory committees, including preliminary guidance on vaccine prioritization that was developed jointly by the U.S. Department of Health and Human Services’ Advisory Committee on Immunization Practices (ACIP) and National Vaccine Advisory Committee (NVAC) in 2005, and findings on critical infrastructures and workforces from an analysis by DHS’s National Infrastructure Advisory Council (NIAC).

Input from Stakeholders and the Public

Public and stakeholder input was obtained in public engagement and stakeholder meetings and from over 200 written comments submitted in response to a Request for Information issued in December 2006. Public engagement and stakeholder meetings focused on discussion of the goals and objectives of pandemic vaccination and their importance. Participants in all-day sessions heard background presentations on pandemics and pandemic vaccination, took part in small group discussions of potential vaccination program goals and objectives as well as the values underlying them, and rated each on a scale from “extremely important” to “unimportant” based on a severe pandemic scenario.

Stakeholders and the public identified the same four vaccination program objectives as most important in all of the meetings:

- Protect persons critical to the pandemic response and who provide care for persons with pandemic illness,
- Protect persons who provide essential community services,
- Protect persons who are at high risk of infection because of their occupation, and
- Protect children.

Other objectives that were considered important included protecting homeland and national security, indirectly protecting persons who cannot be vaccinated, protecting persons at high risk of severe illness and death, protecting those who have essential economic functions, protecting persons guarding our borders, and targeting vaccine to persons among whom it is most likely to be effective.

Decision Analysis

The working group undertook a rigorous decision analysis as part of the process to develop draft guidance. In this analysis, working group members rated the importance of each of 10 potential vaccination program objectives for a severe pandemic. For vaccination program objectives relating to occupational function and risk, working group members independently rated 57 population groups on the degree to which they met each of the objectives. Separately, influenza experts at the U.S. Centers for Disease Control and Prevention (CDC) and in academia independently rated groups with respect to science-based objectives, such as vaccine effectiveness and risk of severe or fatal influenza illness. Weighted scores were totaled across the ten objectives for each group, and groups were ranked in four categories: homeland and national security, health care and community support services, critical infrastructure, and general population. The process was then replicated based on rating of vaccination program objectives for moderate and less severe pandemics.

Groups with the highest overall scores, regardless of pandemic severity, included front-line public health responders, essential health care workers, emergency medical service providers, and law enforcement personnel. Among the general population groups, infants and toddlers ranked highest.

Ethical Considerations

Underlying the working group's deliberations was a strong consideration of the ethical issues involved in allocating vaccine when supply is limited. An ethicist from the National Institutes of Health who participated as a member of the working group and academic ethicists discussed ethical frameworks and their application to decision making on vaccine allocation. Vaccinating some people earlier than others to minimize health and societal impacts of a pandemic was considered ethically appropriate. Other important principles that were considered were: fairness and equity (recognizing that all persons have equal value, and providing equal opportunity for vaccination among all persons in a priority group); reciprocity, defined as protecting persons who assume increased risk of becoming infected because of their jobs; and flexibility to assure that vaccine priorities are optimally tailored to the severity of the pandemic and the groups at greatest risk of severe infection and death.

A second ethical focus was the importance of developing guidance through an open and transparent process with multiple opportunities and avenues for input from the public and stakeholders. Public engagement meetings were held in Las Cruces, New Mexico, and Long Island, New York, and included a diverse group of participants. In addition, stakeholders participated at a meeting in Washington D.C. that included representatives from private sector businesses and community organizations. The working group is committed to maintaining an

ethical process as comments on the draft guidance are sought through a variety of forums and media.

Appendix B Pandemic Severity Index

The Pandemic Severity Index

Priority groups for receipt of vaccine early in a pandemic may differ based on the severity of the pandemic, as defined by the Pandemic Severity Index (PSI). The PSI defines five categories of pandemic severity based on the proportion of persons with pandemic illness who die (the “case fatality rate”). The severity of a pandemic will be determined soon after its initial outbreak by surveillance of cases and their outcomes before large areas of the world are affected.

Government entities will use the PSI to guide implementation of response measures, including vaccination and community strategies to mitigate disease transmission.

Matching the targeting and intensity of intervention to the severity of a pandemic maximizes the public health benefit and avoids adverse consequences. Data on case fatality rates early in the course of the next pandemic will be collected during outbreak investigations of initial clusters of human cases, and public health officials may make use of existing influenza surveillance systems once widespread transmission starts. Other measures of pandemic severity may be assessed and highest risk populations for severe illness and death will be identified.

For additional information on the PSI, please go to <http://www.pandemicflu.gov/plan/community/commitigation.html#IV>.

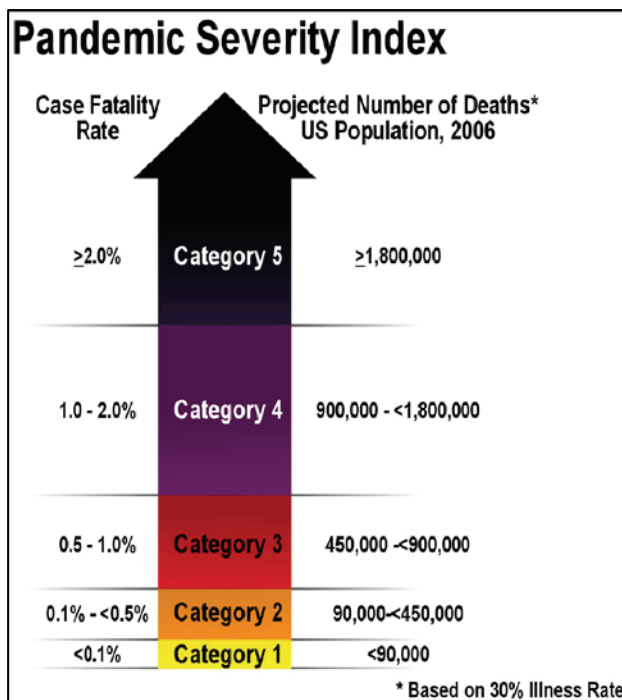


Diagram 1:

Pandemic Severity Index categories based on case fatality rates of pandemic illness. Note that the projected number of U.S. deaths refers to a pandemic in which no response measures are undertaken. Health impacts in the context of an effective response would be much less.

Appendix C

Rationale for Categories of Vaccine-Eligible Groups

Defining groups in four categories – Homeland and National Security, Health Care and Community Support Services, Critical Infrastructure, and General Population – highlights the multiple, important objectives of a pandemic vaccination program and the U.S. Government’s commitment to address different needs simultaneously as the program is implemented. It facilitates tailoring the phased approach to vaccine allocation by pandemic severity, where the key difference in vaccination tiers is when or whether a level (defined as a cluster of groups) in each category will be vaccinated.

Defining target groups in categories also highlights potential differences in program implementation between categories. For example, vaccine for homeland and national security groups may be allocated to the Departments of Defense, Homeland Security, and other agencies and administered by military health care personnel or occupational health providers. Health care providers may be vaccinated in their workplaces. Large companies, particularly those operating in several States, may have the capacity to coordinate the vaccination program for their workers. Vaccination of first responders, critical workers at municipal utilities, and the general population will be managed by State and local health departments.

The Tables below provide further definition of target groups for pandemic vaccination, an estimated size of the group and a brief description of the working group’s rationale for prioritizing that group. Note that persons in defined occupational groups in Homeland and National Security, Health Care and Community Support Services, and Critical Infrastructure categories are only those who are critical to maintaining essential functions. Work is ongoing to further assess and hone definitions and population sizes for these groups.

Table 1. Target groups in Homeland and National Security¹

Level	Group	Definition	Estimated Group Size	Rationale
A	Deployed and mission critical personnel	Military forces and other mission critical personnel not limited to active duty military or USG employees. Includes for example, some diplomatic and intelligence service personnel, and public	700,000	Critical to protect national security; unable to tolerate projected pandemic personnel loss and fulfill mission; potential greater risk of infection due to geographic location and crowded living or

¹ Estimates of group size from Department of Defense, Department of Homeland Security, and from working group representatives from other Federal agencies

		and private sector functions identified by Federal agencies as unique and critical to national security		working conditions
B	Essential support and sustainment personnel	Military and other essential personnel needed to support and sustain deployed forces	650,000	Maintaining function is essential to mission success for deployed personnel; risk of infection may be less from geographical location and living conditions
B	Intelligence services	Critical personnel in the intelligence community serving at domestic and international posts	150,000	Essential to homeland and national security; opportunities for social distancing limited because of inability to telework due to need for secure facilities; some personnel may be at increased risk based on geographical location
B	Border protection personnel	Critical personnel in agencies providing U.S. border security, including but not limited to Customs and Border Protection, Border Patrol, Immigration and Customs Enforcement, Transportation Security Administration, and Coast Guard personnel	100,000	Essential to homeland security; in close contact with many potentially infected persons throughout a pandemic; limited ability to apply social distancing strategies
B	National Guard personnel	National Guard personnel not included above who are likely to be activated to maintain public order during a pandemic or to	500,000	Likely to be activated in a pandemic to support critical response or community functions; may be at increased risk of exposure and

		support pandemic response services or critical infrastructure		infection based on mission
B	Other domestic national security personnel	Includes other groups that are essential to national security such as guards at nuclear facilities	50,000	Essential to national and homeland security
C	Remaining active duty military and essential support personnel	Active duty personnel not included in higher priority groups and essential support personnel	1.5 million	Important to national and homeland security

Table 2. Target groups in Health Care and Community Support Services²

Level	Group	Definition	Estimated Group Size	Rationale
A	Public health personnel	Public health responders at Federal, State, and local levels	300,000	Essential to implementing the pandemic response, including the vaccination program and other pharmaceutical and non-pharmaceutical response measures; also provide care for poor and underserved populations; personnel have a high risk of exposure to persons with pandemic illness
A	Inpatient health care providers	Includes two-thirds of personnel at acute care hospitals who would be identified by their institution as critical to provision of inpatient health care services; primarily will include persons providing care with direct patient exposure but also will include persons essential to maintaining hospital infrastructure	3.2 million	Maintaining quality inpatient health care is critical to reducing mortality from pandemic influenza and from other illnesses that will occur concurrently with the pandemic; inpatient health care burden will be markedly increased during a pandemic; studies show health outcomes are associated with staff-to-patient ratio; personnel have high risk of exposure, including to infectious aerosols; infected health care personnel

² Estimates of group size from Department of Health and Human Services. Community social service provider estimate assumes 300,000 volunteers from national organizations (e.g., Red Cross) and additional allocation of 1 per 1000 population.

				may transmit infection to vulnerable persons hospitalized for non-influenza illnesses
A	Outpatient and home health care providers	Includes two-thirds of personnel identified by their organization at outpatient facilities, including but not limited to physicians' offices, dialysis centers, urgent care centers, and blood donation facilities; and skilled home health care personnel	2 million	Maintaining outpatient and home health care is critical to reducing pandemic mortality and morbidity and reducing the burden on inpatient services; outpatient health care burden will be markedly increased during a pandemic; personnel have high risk of exposure, possibly including to infectious aerosols; infected health care personnel may transmit infection to vulnerable persons receiving care for non-influenza illness
A	Health care personnel in long-term care facilities	Skilled nursing and other essential personnel in LTCFs estimated at about 25% of the overall LTCF workforce	800,000	Essential to provide care to more than 3 million persons in LTCFs who are particularly vulnerable to influenza illness and death; risk of pandemic outbreaks in LCTFs may best be reduced by vaccinating staff and limiting exposure of residents to infection; if outbreaks occur, personnel have high risk of exposure, possibly including to infectious aerosols
B	Community support service personnel	Personnel from community organizations	600,000	Community level support will be critical for persons who are ill

	(emergency management and community and faith-based support organizations)	including the Red Cross who will provide essential support and have direct contact with persons and families affected during community pandemic outbreaks and emergency management personnel who coordinate pandemic response and support activities		and isolated in their homes or are complying with recommendations for voluntary household quarantine during community pandemic outbreaks, for elderly persons who live alone and may be afraid of going out during a pandemic, for persons who are homeless, and for other vulnerable populations; support may include providing food and medications, as well as other social and mental health services; personnel will be at high risk of exposure to ill persons and, if infected could transmit illness to a high-risk population
C	Other important health care personnel	Includes groups that provide important health care services but are at less occupational risk, such as pharmacists, laboratory personnel, and persons providing death care services	500,000	Personnel provide important health care services but are not in as close contact with ill persons and at less risk of occupational infection

Table 3. Target groups in Critical Infrastructure³

Level	Group	Definition	Estimated Group Size	Rationale
A	Emergency services personnel – EMS, fire, law enforcement, and corrections	Includes groups supporting emergency response and public safety. EMS personnel include those who are fire department-based, hospital-based or private; fire fighters include professionals and volunteers; law enforcement includes local police, sheriff officers, and State troopers; and corrections officers include those at prisons and jails	2 million	Provide critical public safety and emergency response services; contribute to pandemic response activities by maintaining public order and contributing to medical care services; increased occupational risk for emergency medical services due to exposure to persons with pandemic illness
A	Manufacturers of pandemic vaccine, antiviral drugs, and other essential pandemic response materials	Includes critical personnel required for ongoing production of pandemic medical countermeasures and other critical medical supplies to support a pandemic response	50,000	Reducing pandemic health impacts requires production of pandemic vaccine, antiviral drugs, and other critical supplies
A	Elected or appointed government leaders	Elected officials at Federal, State, and local levels and critical decision makers in agencies coordinating pandemic response	50,000	Preserving leadership and decision-making capabilities at all levels of government is important for an effective pandemic response and to

³ Estimated group sizes for critical infrastructure sectors are taken from the NIAC report, *The Prioritization of Critical Infrastructure for a Pandemic Outbreak in the United States* (www.dhs.gov/niac). The range presents estimates for the highest priority critical personnel (Tier 1) and all critical personnel (Tiers 1 – 3). Estimates for government personnel currently are being developed

		activities		promote compliance with community mitigation and other response measures
B	Energy (electric and natural gas), communications (telephony and information technology), and water sector personnel (potable and waste water)	Personnel defined by NIAC as being critical in the defined sectors.	1.9 – 4.4 million	These sectors provide products and services that cannot be stored, are required for community health and safety, and are essential to the functioning of other critical infrastructure sectors
B	Critical government personnel	Federal, State, and local government employees and contractors who perform critical regulatory or operational functions required for essential operations of other CI sectors	To be determined	Government personnel are critical for implementing and monitoring components of the pandemic response, and performing regulatory or operational functions essential to critical infrastructures that protect public health and safety and preserve security
C	Transportation, food and agriculture, pharmaceutical, banking and finance, chemical, oil, and postal and shipping sector personnel	Personnel defined by NIAC as being critical in the defined sectors	1.4 – 3.5 million	These sectors provide products and services that can be stored; facilities and personnel are more fungible and, thus, better able to maintain essential functions in a setting of high absenteeism; and other strategies can be implemented to protect workers and reduce absenteeism
C	Other important government personnel	Federal, State, and local government employees and contractors not vaccinated in level B	To be determined	Continuity of key government functions is important to support communities and critical infrastructures

		who perform important government functions included in agency continuity-of- operations plans		
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Table 4. Target groups in the General Population⁴

Level	Group	Definition	Estimated Group Size	Rationale
A	Pregnant women	Women at any stage of pregnancy	3.1 million	Pregnant women are at high risk of severe complications or death from pandemic influenza due to immunological, circulatory, and respiratory changes that occur during pregnancy; vaccinating the pregnant woman also will protect newborn infants due to passive transfer of maternal antibodies
A	Infants and toddlers, 6 – 35 months old	Infants and toddlers in the specified age group	10.3 million	Persons in this age group are at high risk of severe complications or death from pandemic influenza; vaccination may require a lower dose than used to protect older children and adults; antiviral medications are not approved for use in children <1 year old; public values prioritize children highest among groups defined by age and disease status
B (Sub-level 1)	Household contacts of infants under 6 months old	Household contacts of infants under 6 months old	4.3 million	Infants under 6 months old cannot be directly protected by vaccination and

⁴ Estimates of group size based on the U.S. census from 2000 extrapolated to 2006 (<http://www.census.gov/ipc/www/usinterimproj>). The target group “Healthy adults 19 – 64 yrs old” does not include persons defined by occupation and pregnant women who are included in other target groups.

				influenza antiviral drugs are not approved for this age group; therefore, protecting young infants by vaccinating household contacts is the best option; public values prioritize children highest among groups defined by age and disease status
B (Sub-level 2)	Children 3 – 18 years old with a high-risk medical condition	Children in the specified age group with a chronic medical condition that increases their risk of severe influenza disease, including heart and lung diseases, metabolic disease, renal disease, and neuromuscular diseases that may compromise respiratory function, as defined by ACIP recommendations for seasonal influenza vaccination	6.5 million	Children with these conditions are at increased risk of severe complications or death from influenza disease; public values prioritize children highest among groups defined by age and disease status
B (Sub-level 3)	Children 3 – 18 years old without a high risk medical condition	Children in the specified age group not included in level B2	58.5 million	Public values prioritize children highest among groups defined by age and disease status; vaccinating children may reduce transmission of pandemic influenza to household contacts and in communities; if children are protected by vaccine, schools can re-open mitigating secondary adverse consequences of

				closing schools
C	High-risk persons 19 – 64 years old	Adults in the specified age group with a chronic medical condition that increases their risk of severe influenza disease, including heart and lung diseases, metabolic disease, renal disease, and neuromuscular diseases that may compromise respiratory function, as defined by ACIP recommendations for seasonal influenza vaccination	36 million	Adults with these conditions are at high-risk of severe complications or death from pandemic influenza
C	Persons over 65 years old	Elderly adults in the specified age group	38 million	Persons in this group are at high-risk of severe complications or death from pandemic influenza
D	Healthy adults, 19 – 64 years old	Adults in the specified age group not included in level C	121.8 million	Persons in this group lack age, health condition, and occupational rationales for priority pandemic vaccination